CONFIDENTIAL

K092346

510 (K) SUMMARY

JAN - 7 2010

Prepared: January 4, 2010

Submitter: Serim Research Corporation

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Contact: Patricia A. Rupchock
Director of Regulatory Affairs

Device Trade Name: Serim® D-CIDE GTA 1.5% Test Strips

Common or Usual Name: Indicator for glutaraldehyde (GTA) high level disinfectant

Device Classification Name: Chemical Indicators for Liquid Chemical Germicide. (b) Class II (Physical/Chemical Sterilization Process Indicator).

Product Code: JOJ

Class: II

Regulation Number: 21CFR 880.2800

Substantial Equivalence: The Serim D-CIDE GTA 1.5% Test Strip is substantially equivalent to 3M Comply Cold Sterilog 1.5% GTA Test Strips, 3M Health Care, P/N 3983MM; K915170.

Device Description: The device is a qualitative, single use, reagent test strip made up of a 0.20 inch square indicator pad that has been chemically treated to detect GTA. The pad is affixed to one end of a 3.25 inch by 0.20 inch white opaque polystyrene strip.

Intended Use: The Serim® D-CIDE GTA 1.5% Test Strip is a chemical indicator for use in determining whether the concentration of glutaraldehyde, the active ingredient in Rapicide HLD and Sterilant (Medivators Reprocessing Systems), is above or at/below the minimum effective concentration (MEC) of 1.5%

GTA established for this solution.

Technological Characteristics: The Serim® D-CIDE GTA 1.5% Test Strips contain three reacting chemicals, and a background dye. The visual response given by the indicator pad of the test strip is based on the following chemical reactions. Glutaraldehyde reacts with sodium sulfite to form a colorless addition product and a base. The base then reacts with a pH indicator producing a purple color. The indicator pad also contains sodium bisulfite, which reacts with both glutaraldehyde and with the base. When glutaraldehyde concentration is above the 1.5% level (MEC), enough base is produced to result in an irreversible and distinct color change of the indicator pad. Testing of glutaraldehyde solutions well above the MEC level of 1.5% results in a solid purple color on the indicator pad. When the glutaraldehyde concentration is at or approaching the MEC level, the base is neutralized by the sodium bisulfite and the indicator pad will display distinct white areas.

Performance: The performance of the Serim D-CIDE GTA 1.5% Test Strips was evaluated in split samples blind studies and compared to test results obtained with 3M Comply Cold Sterilog 1.5% GTA Test Strips. The performance of the Serim D-CIDE GTA 1.5% Test Strips is substantially equivalent to the predicate device, 3M Comply Cold Sterilog 1.5% GTA Test Strips.

Conclusion: The proposed and predicate devices are all single use indicators used to monitor the glutaraldehyde concentration in specific solutions. The Serim D-CIDE GTA 1.5% Test Strip does not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Patricia Rupchock
Director of Regulatory Affairs
Serim Research Corporation
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Elkhart, Indiana 46514

JAN - 7 2010

Re: K092346
Trade/Device Name: Serim® D-CIDE GTA 1.5% Test Strips
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: December 8, 2009
Received: December 10, 2009

Dear Ms. Rupchock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

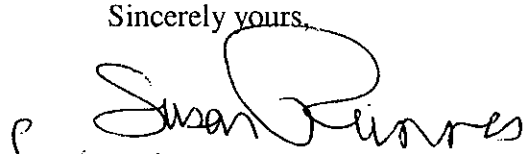
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K092346

Device Name: Serim® D-CIDE GTA 1.5% Test Strips

Indications For Use: The Serim® D-CIDE GTA 1.5% Test Strip is a chemical indicator for use in determining whether the concentration of glutaraldehyde, the active ingredient in Rapicide HLD and Sterilant (Medivators Reprocessing Systems), is above or at/below the minimum effective concentration (MEC) of 1.5% GTA established for this solution.

Prescription Use (Part 21 CFR 801 Subpart D)		AND / OR	Over-The-Counter Use (21 CFR 801 Subpart C)	√

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claman-Wells

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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